

REMARKS

Claims 56-106 are pending. Claims 88-106 are withdrawn. Claims 56-87 are rejected.

Claims Rejections under 35 U.S.C. §102

Claims 56-63, 65, 76-82 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3071135 ("Baldwin"). Applicants respectfully traverse as set forth below.

Claim 56 is directed to a needle in which the "outer edges present on the pointed end in the area from the point to a position beyond the opening are rounded so that after the initial penetration the pointed end will push the membrane material away rather than cutting the membrane material." Rounding of the outer edges prevents coring of a membrane since the needle displaces the membrane material rather than cutting through it. This is particularly significant in situation requiring repeated penetration of a membrane with the needle.

Applicants have amended claim 56 to further clarify that the "outer edges" are rounded "from the point to a position beyond the opening," as clearly shown by and described with reference to numerals 18, 19 and 25 in FIG. 2 and as described in published paragraphs [0040-0041, 0052]. Applicants submit that "beyond the opening" clearly means rearward of the needle opening with reference to the forward tip of the needle as shown in the figures.

In contrast, Baldwin's proposed design seeks merely to leave a core flap attached to the membrane, rather than to prevent coring. Baldwin describes a needle having cutting edges (beveled side faces 13 and 19), which result in cutting of the membrane as the two cutting edges (13 and 19) of the needle create a V-shaped cut each time the needle penetrates the membrane. Baldwin proposes to address coring of a membrane by rounding or dulling only the most rearward **heel** portion of the **inner** edge of the needle opening (heel 18) so that the membrane slides over the heel of the needle opening, effectively producing a flapped membrane core. The flapped core is likely to allow leakage and can still become a loose core upon further membrane cutting and coring with repeated needle penetrations. Thus, Baldwin would lead one of skilled in

the art away from the invention as claimed. Similarly, many prior art needles are deliberately designed with sharp outer edges to minimize pain during penetration of human skin, and thus also would also lead one of skill in the art away from making a needle with rounded outer edges.

Regarding claim 76, the Office Action cites Baldwin as teaching a "point . . . arranged to lie substantially on the longitudinal centre line of the needle," with reference to Baldwin FIG. 6 line 7. A longitudinal centreline, however, is located along the central axis or **radial** centre of the needle. Baldwin's point is formed at the need perimeter and not along the needle centre line. Stated otherwise, the referenced line shown in Baldwin is merely a vertical axis of symmetry or a lateral midpoint of an end view of Baldwin's needle.

Accordingly, Applicants submit that Baldwin does not disclose a "needle . . . wherein the point of the penetrating tip is arranged to lie substantially on the longitudinal centre line of the needle," as recited in claims 58 and 76. Moreover, Baldwin does not disclose such a needle wherein "the penetrating tip is designed with a cross section having a symmetry causing at least three substantially equally sized forces (F) in different directions which are radial to the longitudinal centre line of the needle," as further recited in independent claim 76.

Accordingly, Applicants submit that Claim 56 and its dependent claims 57-75 and 79-87 and Claim 76 and dependent claims 77-78 are patentable over Baldwin and request withdrawal of the rejections under Section 102.

Claims Rejections under 35 U.S.C. §103

Claims 64 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3071135 ("Baldwin") as applied to claims 56 or 58, and further in view of U.S. Patent No. 4958621 ("Topel"). Claims 66-69, 72, 73 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3071135 ("Baldwin") as applied to claims 56, 58 or 65. Claims 70, 71, 74, 75, 85 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3071135 ("Baldwin") as applied to claim 56, 58, 65 or 69, and further in view of U.S. Patent No. 6517523 ("Kaneko"). Applicants respectfully traverse as set forth below.

As discussed with regard to claim 56 above, Baldwin discloses only rounding of the most rearward heel portion of the inner edge of the needle opening to prevent complete separation of a core from a membrane. Topel is cited merely as teaching use of a lancet cut and provides no disclosure of rounded outer edges. Kaneko is cited merely as teaching a particular range of bevel cut angles and provides no disclosure of rounded outer edges.

Neither Baldwin, Topel, Kaneko, nor any combination of the same teach or suggest a needle in which "the outer edges present on the pointed end in the area from the point to a position beyond the opening are rounded," as recited in claim 56. Accordingly, Applicants submit that claim 56 and its dependent claims are patentable over the cited references.

Regarding claim 76 and its dependent claims, Baldwin does not disclose a needle having a point that is arranged to lie substantially on the longitudinal centre line (central axis) of the needle. Instead, the point (14) of the needle described by Baldwin is offset or arranged to lie at a distance corresponding substantially to the outer radius of the needle from the longitudinal centre line of the needle. The penetrating tip of the needle, as claimed, provides at least three substantially equal forces radial to the longitudinal centre line of the needle such that the needle will not deviate from its initial penetration point when the needle penetrates a membrane.

Accordingly, Applicants submit that independent claim 76 and dependent claims 77-87 are patentable over Baldwin.

Accordingly, Applicants request withdrawal of the rejections under Section 103.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this

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paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment. Applicants respectfully request consideration of all filed IDS' not previously considered, by initialing and returning each Form 1449.

No charges are believed due. However, if any fees are due, they are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 19497-0002US1.

Respectfully submitted,

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